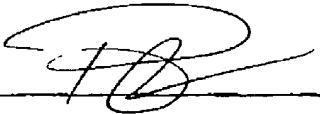


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Attorney Docket No.: 023070-122010US **PATENT**

7-20-04  
By: 

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

HIPOLITO, Ronaldo B. et al.

Application No.: 10/693,112

Filed: October 24, 2003

For: ENDOTRACHEAL TUBE

Customer No.: 20350

Examiner: Teena Kay Mitchell

Art Unit: 3743

DECLARATION PURSUANT TO 37 CFR  
§ 1.132

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Michael P. Sherman of Davis, CA declare as follows:

1. I am a co-inventor in the present patent application.
2. I have reviewed the presently pending claims, and the pending Office Action in the referenced case. I have also reviewed the obviousness rejections based on Yu (U.S. Patent No. 4,774,943) and Sheridan (U.S. Patent No. 3,508,554).

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3. I do not believe that the claims are obvious over the combination of Yu and Sheridan. Embodiments of the invention solve unique problems and produce unexpected results. For example, as noted at page 2, lines 19-22 of the specification, right mainstem bronchial intubation (RMSBI) can cause complications in a patient, and even death in some cases. This is especially true with respect to small patients such as neonates. RMSBI is a potential cause of morbidity during neonatal assisted ventilation (breathing). Embodiments of the invention provide a unique and successful solution to the problem of RMSBI.

4. As noted at page 15, lines 2-6 of the specification, a prospective study was conducted over about a 17-month period. The prospective study randomly assigned infants to one of two groups based on the type of endotracheal tube used and the procedure utilized to ascertain the depth of insertion during oro-tracheal intubation. Group 1 used neonatal endotracheal tubes with single-colored (black) centimeter marks and vocal cord localizer lines (also black). Subjects in Group 1 were enrolled during the odd numbered months of the study. Group 2 had brightly colored lines placed circumferentially at 6.5, 7.5, 8.5 and 9.5 cm from the tip of the endotracheal tube. These subjects were enrolled during the even numbered months of the study. The lines on the endotracheal tube consisted of non-toxic and tightly adherent tape that was 0.25 centimeters wide. Tubes with the adherent colored tape were prepared and gas sterilized before use.

4. I believe that the prospective study shows that embodiments of the invention produce unexpected results and solve the problem of RMSBI. For example, as explained at the carryover paragraph on pages 20-21 of the specification, none of the thirty one patients using an endotracheal tube with colored lines had RMSBI, while eight of thirty-one patients using endotracheal tubes using solid black lines had RMSBI. See also, FIG. 5 in the present application. As shown by the data provided in the specification and at FIG. 5 of the present application, embodiments of the invention are clearly advantageous over conventional endotracheal tubes.


5. The Examiner alleges that it would have been "obvious" to have located the markings on the tube of Yu to employ any placement on the endotracheal tube based on the

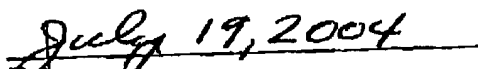
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teachings of Sheridan (page 4 of the Office Action). However, neither Yu nor Sheridan discuss or suggest the problems associated with neonate intubation and RMSBI, or the unexpected results provided by embodiments of the invention. Even assuming *arguendo* that it would have been "obvious" to have modified Yu with the teachings of Sheridan to arrive at the inventions of the pending claims, I believe that the present inventors have provided sufficient evidence of unexpected results in the prospective study to rebut any allegation that the embodiments of the invention are obvious.

6. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

  
Michael P. Sherman

  
Date

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